



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2013-N-0590]

RIN 0910-AG97

Implementation of the Food and Drug Administration Food Safety Modernization Act  
Amendments to the Reportable Food Registry Provisions of the Federal Food, Drug, and  
Cosmetic Act; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the advance notice of proposed rulemaking that appeared in the Federal Register of March 26, 2014. In the advance notice of proposed rulemaking, FDA solicited comments, data, and information to assist the Agency in implementing the FDA Food Safety Modernization Act (FSMA), which added new provisions to the Reportable Food Registry (RFR) requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). We are taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Agency name, Docket No. FDA-2013-N-0590 and/or Regulatory Information Number (RIN) 0910-AG97, by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following way:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA-2013-N-0590, and RIN 0910-AG97 for this advance notice of proposed rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ted Elkin, Center for Food Safety and Applied Nutrition (HFS-008), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 240-402-2428; or April Hodges, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9237.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of March 26, 2014 (79 FR 16698), we published an advance notice of proposed rulemaking with a 75-day comment period to request comments to assist us in implementing FSMA, which added new provisions to the RFR requirements of the FD&C Act. Interested persons were originally given until June 9, 2014, to comment on the advance notice of proposed rulemaking.

We have received a request for a 60-day extension of the comment period for the advance notice of proposed rulemaking. The request conveyed concern that the 75-day comment period did not allow sufficient time to develop a meaningful or thoughtful response to the advance notice of proposed rulemaking particularly in light of other FSMA-related rulemakings for which the Agency is also requesting comments.

We have considered the request and are reopening the comment period for the advance notice of proposed rulemaking for 60 days, until [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. We believe that reopening the comment period an additional 60 days allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

## II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: June 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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